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December 22, 2004

Mail Stop Issue Fee Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Application Serial No. 09/058,323

Filed: April 9, 1998

For:

PROCESS FOR DISCRIMINATING AND COUNTING ERYTHROBLASTS

Our Reference: C010690/0101683

Sir:

Enclosed is a Communication Accompanying Issue Fee Payment, a completed Issue Fee Transmittal Form (PTOL-85b), a check for the issue and publication fees in the amount of \$1,700.00, and a check for \$30.00 for ten soft copies of the patent. In addition, we enclose a copy of the Transmittal of Formal Drawings. Please note that the original drawing transmittal has been forwarded to the Patent Office under separate cover. This copy is being submitted to your office as a courtesy.

If any of our checks are missing or otherwise insufficient, or if any additional fees are required, please charge the fee (or credit any overpayment) to Deposit Account No. 02-4467.

Respectfully submitted,

Charles T. J. Weigell, Reg. No. 43,398

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And Bryan Cave,

A Multinational Partnership,

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(Date of Deposit)

Charles T. J. Weigell
Name of applicant, assignee, or
Registered Representative

Signature

12/22/04

Date of Signature

Docket No.: C010690/0101683



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Berend HOUWEN, <i>et al.</i>)
Serial No. 09/058,323) Examiner: Gailene R. Gabel)) Art Unit: 1641)
Filed: April 9, 1998	

For: PROCESS FOR DISCRIMINATING AND

COUNTING ERYTHROBLASTS

December 22, 2004

SUBMISSION OF FORMAL DRAWINGS

Mail Stop PGPUB Drawings

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Enclosed are seven (7) formal drawing sheets (Figs. 1-11) for the above-captioned

case.

Respectfully submitted,

Charles T. J. Weigell, Reg. No. 43,398

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New York, New York December 22, 2004

COMMUNICATION ACCOMPANYING ISSUE FEE PAYMENT

Mail Stop Issue Fee Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This is in response to the Notice of Allowability and Issue Fee Due mailed September 23, 2004, which set a three-month shortened statutory period for payment of the issue fee. Accordingly, this response is filed timely upon mailing, with an executed certificate of mailing, on or before December 23, 2004. 37 C.F.R. §1.8.

Along with this response, Applicant provides a check for the requisite issue fee along with the Issue Fee Transmittal form. If it is determined that any additional fees are due, please charge such fee to Deposit Account No. 02-4467.

REMARKS

Applicant notes with appreciation a telephone discussion of December 22, 2004, between Supervisory Examiner Long V. Le and the undersigned attorney, regarding the contents of this communication and Applicant's concern that it be fully responsive to the requirement for a "fully executed declaration" made in the Notice of Allowability dated September 23, 2004.

In the Notice of Allowability, the Examiner required Applicant provide a "fully executed declaration", and referencing an objection set forth previously in an Office Action dated September 28, 1999. Reference to that Office Action indicates a prior Examiner objected to the declaration filed with the continuation in part application on April 9, 1998 because it did not include the dates of the inventors' signatures.

Applicant, however, submits the objection raised in the September 28, 1999 Office Action is moot. MPEP § 602.05 states that the Office no longer checks the date of execution of the oath or declaration in an application, and will no longer require a newly executed oath or declaration "where the date of execution has been omitted". See MPEP § 602.05, at 600-36 (8th Ed., 2001, Rev'd 2003). Given this, Applicant believes the original declaration signed by all inventors should be accepted and the objection withdrawn.

However, although Applicant believes the objection and resulting requirement for a new declaration having dated signatures should no longer be applicable, out of an abundance of caution to ensure the application is advanced to issuance Applicant encloses herewith:

- i.) A copy of the original signed declaration which was filed with the Application on April 9, 1998, as received from Berend Houwen and bearing an executed notary form attesting to and demonstrating signature of the declaration on April 6, 1998 by Berend Houwen (now deceased--please see copy of obituary article also enclosed) and Fu-sheng Wang; and
- ii.) A supplemental declaration referencing all named inventor signature blocks, and signed by the remaining three inventors whose original declaration signatures were undated.

Applicant submits these enclosures account for all five inventors who signed the original declaration and satisfy the requirement for dated signatures. Therefore, and notwithstanding the provisions of MPEP §602.05, should the Office deem the objection to the original declaration is still applicable (though Applicant strongly believes it is not), Applicant submits

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that the enclosures submitted obviate and/or remedy the objections raised as to the Application declaration.

CONCLUSION

In view of the foregoing, favorable action and issuance of this application, respectfully is solicited.

If the Examiner has any questions regarding this paper, please contact the undersigned attorney.

Respectfully submitted,

Charles T. J. Weigell, Reg. No. 43,398

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(Date of Deposit)

Charles T. J. Weigell

Name of applicant, assignee, or Registered Representative

Signature

December 22, 2004

Date of Signature

ABOUT MEMBERSHIP GROUPS JOURNAL EVENTS DIRECTORS CORPORATE CONTACT

Dr. Berend Houwen, Founder THE INTERNATIONAL SOCIETY FOR LABORATORY HEMATOLOGY



The ISLH BEREND HOUWEN Annual Lecture

In recognition of the years of selfless dedication that Berend has given the field of laboratory hematology, ISLH has created the Berend Houwen Annual Lecture.

This lecture will be given annually at the ISLH meeting to an individual who has made a significant contribution to the field of laboratory hematology thorough research, invention, or education, thereby embodying the contributions and dedication exemplified by Berand Houwen.

Those colleagues, students, and friends of Berend wishing to make a memorial contribution to ensure the perpetuation and prestige of this award honoring the man that gave so much of himself to laboratory hematology may make a secure online contribution or send contributions by clicking below.

ISLH executive office

With a notation that the gift is for the Berend Houwen Memorial Fund.

Berend Houwen, MD, PhD

The field or discipline of laboratory hematology lost a true leader and visionary on 26 February 2004, with the untimely death of Dr. Berend Houwen. He succumbed to a sudden cardiac event on his way to work in his continuing effort to improve the practice of laboratory hematology as Medical Director for Beckman Coulter. His passing away caused the loss of a mentor, colleague, and friend to all of us fortunate enough to have been touched by him.

Berend was raised and educated in the Netherlands. He received his medical education, PhD, and training as an internist and hematologist at the Universities of Groningen and Leyden. Following further post-doctoral training in oncology in Manchester, England and a faculty position at University of Groningen he crossed the pond to North America. Berend served as Director of the Clinical and Experimental Hematology Laboratories at Foothills Hospital and University of Calgary, Alberta, Canada for most of the 1980s. It is during this period that Berend began his crusade to formalize laboratory hematology as a discipline and initiated the embryo that would eventually mature into the International Society for Laboratory Hematology (ISLH). Berend saw the need for communication between academicians, manufacturers and practitioners of diagnostic hematology. Toward this end he organized annual Technological Innovations in Laboratory Hematology meetings in the beautiful setting of Banff, Alberta, Canada. These meetings brought together experts from around the world to discuss the coming advances in laboratory hematology, a truly practical forum of bringing the research bench to clinical practice.

It was through these Banff meetings that I developed a lasting professional and personal relationship with Berend that would eventually lead to the formation of ISLH and this journal. I was then trying to advance the concept that reticulocyte maturation as measured by thiazole orange fluorescence and flow cytometry could add a new dimension to the evaluation of anemia and erythropoiesis. Berend not only immediately understood the concept that reticulocyte maturation parameters could provide a more sensitive and earlier indicator of erythropoletic activity, but additionally recognized the need for establishing standardization of the measurements and the challenge of educating both laboratorians and clinicians. Together we planned and executed inter-laboratory studies, international consensus discussions, and finally achieved the acceptance of the immature reticulocyte fraction or IRF, a reticulocyte parameter now cleared by the FDA as a diagnostic parameter available on automated hematology instruments manufactured by four different hematology instrument companies. As eloquently argued by Berend in his excellent review on reticulocyte maturation (1), the IRF represented a truly improved parameter for anemia evaluation and patient management, which would not have entered the main stream of laboratory hematology practice were it not for his persistence and vision. This is but one example of his contribution to the field, as documented in his over 200 scholarly publications and presentations, multiple patents in automated hematology, and most importantly the people whose lives he touched.

His contributions included stem cell enumeration, hemoglobin measurements, improved methods for leukocyte differential counting, and reticulated platelet counting to name his most recent activities. Although he rarely talked of his days as a clinical hematologist, he was involved in advancing the use of multiple drug therapy for multiple myeloma and performed bone marrow transplantation to treat acute leukemia long before it was an established technique. He was also one of the

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early investigators to apply multi-parameter flow cytometry to the study of disease, describing the use of a two color flow cytometric method to study cell cycle in myeloma, long before was proliferative activity described as an important prognostic indicator by others (2). I can vividly recall the few occasions when I took an authoritative tone in talking with Berend about flow cytometric analysis of blood cells, when he would in his unique style point out to me that he too had a bit of experience in the area. His work with this technology continued to this day, as he was actively involved in an international Council for Standardization in Haematology (ICSH) initiative to develop an immunophenotypic reference method for blood cell differential counts to replace the current manual microscopic counting standard (NCCLS H-20).

Berend's contribution to the field of laboratory hematology went well beyond his scholarly publications and clever discoveries. He had true vision of what could be achieved and accomplished through education and consensus building. The two best examples of this are ISLH and the Laboratory Hematology journal. After his move from Calgary south of the 48th parallel, accompanied by his wife, soul mate and golf partner Cathy, he saw the need to formalize laboratory hematology as a true disciple. His professional positions in the U.S were first in a sabbatical year with Dr John Koepke at Duke Univ. In North Carolina, then to California as a faculty member at Loma Linda University, Medical Director for Sysmex, and more recently as Medical Director at Beckman Coulter. Throughout these academic and corporate roles Berend and others organized several Technological Innovations in Laboratory Hematology meetings and began convinced that the interest and enthusiasm that occurred around these meetings could and should be formalized as ISLH. Our only disagreement at the time was whether it should be the society "of" or "for" hematology.

Those that knew Berend can accurately predict that his choice was "for" and so it was. So in 1992 ISLH was born and through those early years he even made personal loans to ISLH to cover various shortfalls for meeting expenses. Gradually ISLH has evolved to a membership of nearly 1000 professionals from countries around the world. His vision for ISLH was more than a fellowship of laboratory professionals and a structure for educational forums. Although he was active in standardization organizations, such as NCCLS and ICSH, Berend saw that ISLH could effectively serve as an International voice for defining the practice standards and regulatory guidelines of laboratory hematology. Examples of such, which served to benefit both the practitioners of and manufacturers for the field, included the extended differential task force, immunoplatelet count working group (3), and the reticulated platelet task force. All these efforts were initiated by Berend and resulted in positive change that allowed technologic innovation to enter clinical practice.

The second vision Berend had was the belief that ISLH should have a journal from which to disseminate advances in laboratory hematology. Following discussions with Bill Carden of Carden Jennings Publishers and after several rounds of negotiations Lab Heme was born. As this issue celebrates, the journal is now 10 years old and under the editorship of Ken Ault is a respected, "indexed" journal - Berend's child has grown to be something he was deservedly proud of. Although Lab Heme and ISLH are now ably managed and guided by others and will continue to grow and evolve, just as Berend had hoped, these entities and resources to the laboratory hematology community would not have come about without the vision, dedication, guidance, and support of Berend Houwen.

In recognition of the years of selfless dedication that Berend has given the field of laboratory hematology, ISLH has created the Berend Houwen, MD, PhD Annual Lecture. This lecture will be given annually at the ISLH meeting to an individual who has made a significant contribution to the field of laboratory hematology thorough research, invention, or education,

FROM

thereby embodying the contributions and dedication exemplified by Berend Houwen. Those colleagues, students, and friends of Berend wishing to make a memorial contribution to ensure the perpetuation and prestige of this award honoring the man that gave so much of himself to laboratory hematology may send contributions to the ISLH executive office with a notation that the gift is for the Berend Houwen Memorial Fund.

Bruce H. Davis, M.D.

NOGAWA PATENT OFFICE

Trillium Diagnostics, LLC and Maine Medical Center Research Institute Scarborough, Maine USA

References:

Houwen 8: Reticulocyte Maturation (Review). Blood Cells 18:167-186, 1992.

Houwen B, van Montfort H. van Montfort LH, Scarffe JH: Flow cytometry of human myeloma cells: Simultaneous cell cycle analysis and myeloma cell identification by a double label technique. Eur J Basic and Applied Histochem. 24:376, 1980 Harrison P, Ault KA, Chapman S, Charle L, Davis BH, Fujimoto K, Houwen B, Kunicka J, Lacombe F, Machin S, Raynor R, van Hove L, and van Assendelft OW: An interlaboratory study of a candidate reference method for platelet counting. Amer J Clin Pathol 115:448-459, 2001